

The Rejection under 35 U.S.C. 112, second paragraph

Claims 1 and 6 (and all dependent claims) are rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite.

Claims 1 and 6, which recited "suitable" have been alleged to be indefinite for that recitation. The Patent Office has stated that if the term means that condition necessary to produce the intended result then "suitable" is redundant.

Without acquiescing to this rejection and in view of the Examiner's comments regarding "suitable", Applicants have not recited suitable in new claims 11 and 17, which have replaced as-filed claims 1 and 6. Accordingly, the withdrawal of the rejection under 35 U.S.C. 112, second paragraph is respectfully requested.

The Rejections under 35 U.S.C. 102

Claims 1-2 and 4 have been rejected under 35 U.S.C. 102(a) as allegedly anticipated by WO 96/39431. Applicants respectfully traverse this rejection.

The Patent Office has alleged that WO 96/39431 teaches a method for producing cells for implanting at the site of a bone infirmity comprising transforming a human host cell with DNA encoding a BMP.

WO 96/39431 teaches sequences encoding BMP-10, methods for production (*in vitro*).

For improved clarity and without acquiescing to this rejection, new claims 11-16, which replace as-filed claims 1-5, specifies that the human cell into which the BMP-encoding DNA is introduced is a progenitor cell and that the BMP to be expressed is BMP-2. By contrast, WO 96/39431 teaches transformation of BMP-10 coding sequences. The amendment of the present application to specify BMP-2 distinguishes over WO 96/39431. Accordingly, the withdrawal of the rejection is respectfully requested.

Claims 1-10 have been rejected under 35 U.S.C. 102(e) as allegedly anticipated by U.S. Patent No. 5,763,416. Applicants respectfully traverse this rejection.

As noted above, claims 1-10 have been canceled without prejudice, and entry of new claims 11-23 has been requested. Applicants respectfully maintain that the 5,763,416 patent is focused on the *in situ* genetic engineering of cells *in situ* to produce bone morphogenetic proteins. There is no specific and enabling disclosure of the introduction of a DNA molecule encoding a BMP, specifically BMP-2 as recited in claim 1, into human progenitor cells *in vitro* with a step of culture prior to implantation at the site of a bone lesion. Neither is there any disclosure of any particular cell line as recited in claims 17, 20 and 22 in the present case.

In view of the above, U.S. Patent No. 5,763,416 does not anticipate the invention as claimed, and the withdrawal of this rejection is respectfully requested.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by WO 95/22611. Applicants respectfully traverse this rejection.

It has been alleged that WO 95/22611 teaches a method for producing cells for implantation at the site of a bone infirmity in a human, comprising transforming a human cell with a DNA encoding a BMP and culturing such cells.

Without acquiescing to the rejection, new claims 11 and 17, which generally correspond to as-filed claims 1 and 6, better state the subject matter of the present invention. The instant claims as amended recite that progenitor cells are genetically engineered to express BMP-2 and cultured to produce cells for implantation. This has not been demonstrated by the cited patent publication.

In view of the foregoing, Applicants respectfully request withdrawal of this rejection.

Conclusion

In view of the foregoing, it is submitted that this case is in condition for allowance, and passage to issuance is respectfully requested.

If there are any outstanding issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

This amendment is accompanied by a Petition for Extension of Time (three months) and a check in the amount of \$870 as required under 37 C.F.R. 1.17. It is believed that this amendment does not necessitate the payment of any additional fees under 37 C.F.R. 1.16-1.17. If the amount submitted is incorrect, however, please charge any deficiency or credit any overpayment to Deposit Account No. 07-1969.

Respectfully submitted,



Donna M. Ferber
Reg. No. 33,878

GREENLEE, WINNER AND SULLIVAN, P.C.
5370 Manhattan Circle, Suite 201
Boulder, CO 80303
Telephone (303) 499-8080
Facsimile: (303) 499-8089
Email: winner@greenwin.com

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